OCT 2 2 2003

K031875

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1.3 [510(k) Summary]

Inter-Os Technologies, Inc.
7430 E. Park Meadows Drive, Suite 300
Lone Tree, CO 80124

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Lone Tree, CO 80124

Contact:
Randolph C. Robinson, MD, DDS
303-708-8390 voice
303-790-7322 fax

Summary Prepared: May 15, 2003

Device Identification:

Trade Name:	Inter-Os Limb Lengthener
Common Name:	Internal Bone Plate Distractor
Classification Name:	Single/Multiple component metallic bone fixation appliance and accessories, 21 CFR 888.3030

Product Description:
The Inter-Os Limb Lengthener is an implantable device used to treat conditions where bone length is deficient. It is used for distraction osteogenesis techniques in the femur and is intended to be implanted by orthopedic surgeons. The device is removed after distraction is complete. It features two telescoping component bone plates that are distracted apart by a threaded drive shaft. Activation of the drive shaft is by means of a transcutaneous pin, which may be removed once the distraction phase is complete. The Activation Pin and the drive shaft are articulated using an internal gear.

All of the components of the Inter-Os Limb Lengthener are fabricated from stainless steel. The Inter-Os Limb Lengthener is intended to be sold non-sterile. It is a single-use device. Sterilization instructions are included in the labeling.

Indications for Use
The Inter-Os Limb Lengthener is an implantable device for distraction osteogenesis techniques in the femur. The Inter-Os Limb Lengthener is used to treat conditions for limb length deficiencies involving the femur. The types of deformities that fall into this category are:

> Traumatic deformities, growth deformities, deformities secondary to tumors and infections, and congenital deformities.

The Inter-Os Limb Lengthener is intended to be used in the upper leg bones of the appendicular skeleton. The Limb Lengthener is not intended to be used for the spine.

The Inter-Os Limb Lengthener is intended for single use and is not meant for repeat sterilization and implantation. The device is to be removed after consolidation of the bone is complete. It is to be used with other commercially-available accessory devices, such as bone screws for fixation to the bone surface. Bone cement is not to be used to fixate the device to the bone; however, commercially-available bone cement may be used on the undersurface of the device to level or stabilize it on a curved surface, or bone cement may also be used to fix the gear in position during the consolidation period.

Predicate Devices

The Inter-Os Limb Lengthener is compared to the Inter-Os Bone Generator (#K993869), Synthes Fixation Plates (#K982222 and K020872), the EBI X-Fix DFS Rail System (#K991941, K000083, K010437, and K021031), the Orthofix/Orthodyne ISKD (#K010322) and others. We believe the Inter-Os device to be substantially equivalent based on the descriptive characteristics, same intended use, and same principle operation of distraction osteogenesis.

Performance has been substantiated by mechanical tests in conformity to standard testing guidelines for equivalent devices and literature review.

CONCLUSION

Based on the design, materials, function, intended use, the Inter-Os Limb Lengthener is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. The Inter-Os Limb Lengthener raises no new safety or effectiveness issues. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Randolph C. Robinson, M.D., D.D.S.
President
Inter-Os Technologies, Inc.
7430 E. Park Meadows Drive, Suite 300
Lone Tree, CO 80124

Re: K031875
Trade/Device Name: Inter-Os Limb Lengthener
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: September 2, 2003
Received: September 3, 2003

Dear Dr. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2 Indications Enclosure

510(k) Number: ~~Pending~~ K031875

Device Name: Inter-Os Limb Lengthener

Intended Uses/Indications

The Inter-Os Limb Lengthener is an implantable device for distraction osteogenesis techniques in the femur. The Inter-Os Limb Lengthener is used to treat conditions for limb length deficiencies involving the femur. The types of deformities that fall into this category are:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X Over-The-Counter Use ____

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031875